

**Amendments to the Specification:**

**Please replace the paragraph beginning at page 2, line 22 with the following rewritten paragraph:**

In some embodiments, sensors developed in accordance with the invention are intended for use in the subcutaneous glucose monitoring system described in U.S. Patent No. 6,175,752 ~~Application Serial No. 09/070,677~~, incorporated herein by reference, although they can be used with other devices and for monitoring other analytes in other parts of the body.

**Please replace the paragraph beginning at page 4, line 8 with the following rewritten paragraph:**

The structure of the subcutaneously implanted portion of one embodiment of a sensor 100 is shown schematically in Figure 1. The drawing is not to scale. The portion of the sensor 100 containing the contact pads (not shown) for the electrodes 104 and 108, which sits on the skin of a user, is not shown but can be the same as that disclosed in U.S. Patent No. 6,175,752 ~~Application Serial No. 09/070,677~~.

**Please replace the paragraph beginning at page 4, line 28 and extending to page 5 with the following rewritten paragraph:**

The working electrode 104 is formed on the base layer 112 or the top layer 116. Materials and processes for forming working electrodes 104 are known to those skilled in the art, including those materials and processes identified in U.S. Patent No. 6,175,752 ~~Application Serial No. 09/070,677~~ and U.S. Patent No. 6,103,033 ~~Application Serial No. 09/034,422~~, both of which are incorporated herein by reference. Suitable materials for working electrodes 104 include, for example, carbon, gold, platinum, palladium and other non-corroding, conductive materials. Suitable methods of depositing the conductive material, include, for example, screen printing, ink jet printing, lithographic processes, sputtering, or any other method of forming a

conductive film on a surface so that its components do not leach into the body, including those described, for example, in U.S. Patent No. 6,103,033 ~~Application Serial No. 09/034,422~~.

**Please replace the paragraph beginning at page 5, line 28 and extending to page 6 with the following rewritten paragraph:**

On or near the working electrode 104 one or more sensing layers 134 are deposited, which transduce the analyte concentration into an electrical signal. A suitable sensing layer 134 includes, for example, an enzyme hydrogel, e.g., a redox polymer, an enzyme, and a cross-linker. Suitable sensing layers 134 include those described in U.S. Patent ~~Application Serial Nos.~~ 6,175,752, 6,143,164 (which is a continuation of abandoned application 08/795,767), and 6,338,790 ~~09/070,677, 08/795,767, and 09/295,962~~, and in U.S. Provisional Patent Application No. 60/165,565, which are all incorporated herein by reference. It is preferred that the sensing chemistry be non-leachable, e.g., that no toxic, immunogenic or operationally essential materials (e.g., mediators or enzymes) leach out from the sensing layer 134 while it is implanted in the body. Such a non-leachable layer may include, for example, enzyme and/or redox mediator that is immobilized on the sensor via crosslinking, entrapment or chemical bonding. However, many other sensing chemistries are feasible, such as the peroxide sensing chemistry described below. As an example, in one embodiment, suitable sensing layer 134 thicknesses are less than 80  $\mu\text{m}$ , less than 50 $\mu\text{m}$ , or less than 20 $\mu\text{m}$  when the sensing layer is hydrated.

**Please replace the paragraph beginning at page 7, line 11 with the following rewritten paragraph:**

The sensor 100 typically includes a counter electrode, a reference electrode, or a combined counter/reference electrode 108. One example of a suitable counter/reference electrode 108 is a silver/silver chloride electrode. Alternatively, instead of implanting the electrodes 108, the counter or counter/reference electrodes 108 can be placed on the skin using, for example, a silver/silver chloride EKG electrode. As used herein, the terms "counter electrode" and "reference electrode" include a combined counter/reference electrode. Counter or

reference electrodes may be formed using a variety of materials and processes known in the art, including those in U.S. Patent ~~Application Serial No. 09/070,677~~ and U.S. Patent Application ~~Serial No. 09/034,422~~ Nos. 6,175,677 and 6,103,033. These materials and processes can be the same as those used to form the working electrode described above.

**Please replace the paragraph beginning at page 8, line 17 with the following rewritten paragraph:**

One approach to minimize the contribution of interferants to current is to select a redox polymer having an oxidation potential that precludes the oxidation of interferants such as acetaminophen or urate. The selection of redox polymers that enable working electrode operation at less than +150 mV versus Ag/AgCl can reduce or prevent oxidation of acetaminophen, urate, and ascorbate. Redox polymers described in U.S. Provisional Patent Application Serial No. 60/165,565 and U.S. Patent ~~Application Serial No. 09/295,962~~, No. 6,338,790, both of which are incorporated herein by reference, are suitable.

**Please replace the paragraph beginning at page 10, line 24 and extending to page 11 with the following rewritten paragraph:**

Yet another embodiment of a sensor 400 of the present invention is illustrated in Figure 4. The sensor 400 includes a sensor body 401 including an outer layer 452, a working electrode 404, a reference electrode 408, and a sensing layer 434. In this embodiment, the working electrode 404, reference electrode 408, and sensing layer 434 are formed in the insulating layer or outer jacket 452. The sensing layer 434, working electrode 404, and reference electrode 408 are exposed at a distal edge 424 of the body. The sensing layer 434 is exposed such that it can come in contact with fluids exposed to the distal edge 424 of the sensor. Such a sensor 400 may be built to very tight tolerances in high volumes with high reproducibility and at a low cost using plastic production methods, such as extrusion molding and injection molding. The working 404 and reference 408 electrodes can be conductive materials or can include plastic or resin which serves to bind conductive materials, such as carbon, gold, platinum, palladium, silver and others

known to those skilled in the art. A suitable plastic is styrene elastomer (RTP 2799X66439 black, L.N.P. Plastics, Chicago, IL). The working electrode 404, counter electrode 408 and outer jacket 452 can be co-extruded using existing techniques. While a cylindrical sensor 400 is illustrated many other geometries are suitable, including planar sensors. Such a sensor can be used either *in vivo* or *in vitro*. It can be operated using an amperometric or coulometric method. Such a sensor and production process is suitable, for example, for the *in vitro* coulometric sensors described in U.S. Patent No. 6,338,790 ~~Application Serial No. 09/295,962~~, "Small Volume *In Vitro* Analyte Sensor with Diffusible or Non-leachable Redox Mediator," incorporated herein by reference. A particular advantage of such manufacturing processes for such sensors is the ability to provide the very reproducible thin layer cell described in the patent application.

**Please replace the paragraph beginning at page 12, line 8 with the following rewritten paragraph:**

Sensors embodying the invention can operate in the same manner as the sensor described in U.S. Patent No. 6,175,752 ~~Application Serial No. 09/070,677~~. The sensor can be operated in an amperometric or coulometric method and can directly substitute for the sensor described in U.S. Patent No. 6,175,752 ~~Application Serial No. 09/070,677~~. The sensor also operates in the analyte monitoring system described in U.S. Patent No. 6,175,752 ~~Application Serial No. 09/070,677~~.

**Please replace the paragraph beginning at page 12, line 16 with the following rewritten paragraph:**

Sensors embodying the invention can be designed for high-volume manufacturing processes, including both batch processes and continuous processes. In a batch process, the sensors are formed on cards or sheets. In a continuous process, the sensors can be formed on a web with the electrodes being a repeated pattern along the running axis of the web. The sensors are designed to be manufactured using known manufacturing process steps, such as electrode

screen printing on the bottom or top layers, nano-scale reagent deposition, coating and curing the top layer, lamination of sheet materials, and cutting of the sensors from the sheets or rolls. The sensors may also be made using extrusion processes. The sensors can be made using manufacturing techniques described in U.S. Patent No. 6,103,033 ~~Application Serial No. 09/034,422~~ and in U.S. Patent No. 6,338,790 ~~Application Serial No. 09/295,962~~, both of which are incorporated herein by reference.

**Please replace the paragraph beginning at page 20, line 25, and extending to page 21 with the following rewritten paragraph:**

Eight sensors were constructed ~~constructed~~ as above, and were operated in phosphate buffered saline, 20mM phosphate, 100 mM chloride, pH 7.1, at 20 mM glucose for 43 hours. Calibration data was taken before and after the 43 hour operation of each of the eight sensors. Figure 7 shows the calibration curve for each of the sensors before the 43 hour operation, and Figure 8 shows the calibration curve for each of the sensors after the 43 hour operation. The sensors demonstrated acceptable stability and were sensitive even at higher glucose concentrations. Sensitivity was excellent, about 1-3 nA / mM glucose in the 5 to 30 mM glucose range. Figure 9 shows the decline in signal of each of the eight sensors during the 43 hour experiment. The decay rate averaged 0.87 %/ hour.